K132743

**Harvesting Cannula**
**510(k) Summary**
Prepared in accordance with 21 CFR Part 807.92

**510(k) Number:** KXXXXXX K132743

**Date Prepared:** 30 August 2013

DEC 03 2013

**Device Owner:**
MAQUET Cardiovascular LLC
45 Barbour Pond Drive
Wayne, New Jersey 07470

**Contact Personnel:** Mark Dinger
**Title:** Regulatory Affairs Specialist II
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**Trade Name:** Harvesting Cannula

**Device Generic Name:** Harvesting Cannula

**Classification:** According to 21 CFR 878.4400 of the Federal Food, Drug and Cosmetic Act, the device classification is Class II, Product code GEI.

**Predicate Device:** K052274 Guidant VasoView HemoPro Endoscopic Vessel Harvesting System (SE: 21 September 2005)

**Device Description:** The Harvesting Cannula has four lumens which house the Endoscope, C-Ring, distal lens washer tube and VASOVIEW Harvesting Tool for cutting and sealing of vessel branches. The C-Ring with the built in distal lens washer is independently controlled by a C-Ring Slider on the handle of the Harvesting Cannula. The C-Ring retracts the vessel and washes the distal tip of the Endoscope. The Harvesting Tool can be inserted, removed, rotated, extended, and retracted from the main Harvesting Cannula through the Tool Adapter Port.

**Indications for Use:**

The VASOVIEW System is indicated for use in minimally invasive surgery allowing access for vessel harvesting, and is primarily indicated for patients undergoing endoscopic surgery for arterial bypass. It is indicated for cutting tissue and controlling bleeding through coagulation, and for patients requiring blunt dissection of tissue including dissection of blood vessels, dissection of blood vessels of the extremities, dissection of ducts and other structures in the extraperitoneal or subcutaneous extremity and thoracic space. Extremity procedures include tissue dissection/vessel harvesting along the saphenous vein for use in coronary artery bypass grafting and peripheral artery bypass or the radial artery for use in coronary artery bypass grafting. Thoracoscopic procedures include exposure and dissection of structures external to the parietal pleura, including nerves, blood vessels and other tissues of the chest wall.

**Technological Characteristics**

The Proposed Harvesting Cannula and the predicate devices have the following similarities:

- the same intended use,
- the same operating principles,
- same labeling,
- incorporates the same basic design,
- sterilized using the same materials and processes,
- same materials,
- has same packaging.

The Proposed Harvesting Cannula and the predicate devices have the following differences:

- C-Ring Tube – Addition of a rib to the C-Ring Tube as well as tube length change (to accommodate for the C-Ring Tube Rib design).
- Blunt Tip – C-ring tube channel revision.
- Scope Wash Tube – Scope Wash Tube length changed (to accommodate for new C-Ring Tube Rib design).

This difference is not considered a technological difference and is substantially equivalent to the predicate devices.

**Safety and Performance:**

MAQUET Cardiovascular's development process required that the following activities be completed during the development of the Harvesting Cannula:

- Performance testing
- Shelf life testing

The results of the in-vitro tests conducted demonstrate that the functionality and performance characteristics of the device are comparable to the currently marketed Harvesting Cannula.

**Conclusion:**

Based upon the information submitted in this Traditional 510(k) premarket notification, MAQUET's Harvesting Cannula is substantially equivalent to the currently marketed Harvesting Cannula. The Harvesting Cannula is similar to the predicate devices in the intended use and the fundamental scientific technology of the device. The design verification and validation testing established that the Harvesting Cannula is substantially equivalent as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

MAQUET Cardiovascular LLC
Mr. Mark Dinger
Regulatory Affairs Specialist II
45 Barbour Pond Drive
Wayne, New Jersey 07470

December 3, 2013

Re: K132743
Trade/Device Name: Harvesting Cannula
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 27, 2013
Received: September 30, 2013

Dear Mr. Dinger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joshua C. Nipper -S

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
For Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
*See PRA Statement on last page.*

510(k) Number *(if known)*
K132743

Device Name
Harvesting Cannula

Indications for Use *(Describe)*
The VASOVIEW System is indicated for use in minimally invasive surgery allowing access for vessel harvesting, and is primarily indicated for patients undergoing endoscopic surgery for arterial bypass. It is indicated for cutting tissue and controlling bleeding through coagulation, and for patients requiring blunt dissection of tissue including dissection of blood vessels, dissection of blood vessels of the extremities, dissection of ducts and other structures in the extraperitoneal or subcutaneous extremity and thoracic space. Extremity procedures include tissue dissection/vessel harvesting along the saphenous vein for use in coronary artery bypass grafting and peripheral artery bypass or the radial artery for use in coronary artery bypass grafting. Thoracoscopic procedures include exposure and dissection of structures external to the parietal pleura, including nerves, blood vessels and other tissues of the chest wall.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Long H. Chen -A

Digitally signed by Long H. Chen -A
DN: cn=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Long H. Chen -A, 0.9.2342.19200300.100.1.1=13003669058
Date: 2013.12.02 08:44:22 -05'00'

for BSA

(Division Sign-off)
Division of Surgical Devices

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